REMARKS

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith.

I. Formal Matters – The Now Pending Claims

Claims 73-106 and 108-111 are now pending. Claims have been amended, and withdrawn-from-consideration-claim 107 has been cancelled, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that the claims, as originally presented and as amended herein, are patentably distinct over the art, and that those claims were in full compliance with the requirements of 35 U.S.C. 112. The amendments and the remarks made herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112. Rather, the amendments and remarks are made simply for clarification (e.g., for grammatical improvement) and to round out the scope of protection to which Applicant is entitled.

II. The Section 112 Rejections Are Overcome

Claims 73-106 and 108-111 were rejected under 35 USC 112, second paragraph, due to certain terms; and, claims 73-106 and 108-111 were rejected under 35 USC 112, first paragraph due to the assertion that the specification is enabled as to the antibody described in Example 2.2, and due to the terms "derived" and "comprises". These rejections are overcome and are addressed collectively.

The claims no longer contain the terms which formed the bases for the Section 112, second paragraph rejection.

The claims are also directed to a first polypeptide which binds specificially in a western blot analysis with a polyclonal rabbit antibody raised against a second polypeptide having an apparent molecular weight of 13 kDa as determined by SDS PAGE followed by visualization, as in the Examples.

And, the claims involving the first polypeptide employ the transitions "consisting essentially of" or "consists essentially of" which are used in the sense attributed to these terms in patent law. These transitions occupy a middle ground between "comprises" and "consists of". They allow for elements not explicitly recited, but exclude elements that are found in the prior

art or that affect a basic or novel characteristic of the invention. *See, e.g., In re Garnero,* 162 U.S.P.Q. 221 (C.C.P.A. 1969); *Ex parte Shepherd*, 185 U.S.P.Q. 480 (BOPA 1974); *Ex parte Hutchins,* 157 U.S.P.Q. 167 (BOPA 1967); *see also Zeigler v. Phillips Petroleum Co.,* 177 U.S.P.Q. 481 (5th Cir. 1973).

Thus, these transition terms provide that the first and second polypeptides do not encompass polypeptides that do not have the basic or novel characteristics, contrary to the concerns expessed at page 4 of the Office Action.

Also, as to the assertions in the Office Action, especially at page 4 of the Office Action, the various epitopes identified in claim 78 and hence identified in the application, shows that epitopes are not "unknown".

Accordingly, pursuant to MPEP 2144.03, Applicants are seasonably challenging the statements in the Office Action made with respect to the Section 112, rejections.

Reconsideration and withdrawal of the Section 112 rejections are respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview, is respectfully requested, with the Examiner and his SPE; and, the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the amendments and remarks herewith, Applicants have addressed and overcome all of rejections of the application set forth in the Office Action, and the present application is in condition for allowance.

Thus, early and favorable reconsideration and withdrawal of the rejections of the application as set forth in the Office Action, and, prompt issuance of a Notice of Allowance of claims 24-70, or an interview with supervisory review, i.e., an interview including SPE Amy Nelson, at an early date, with a view towards reaching agreement on allowable subject matter, are earnestly solicited.

Respectfully submitted,
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APPENDIX: MARKED VERSION OF AMENDMENT

Kindly amend the application, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any etoppel as to equivalents, as follows:

IN THE CLAIMS

Kindly amend the claims, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows:

73. (Amended) An isolated first polypeptide which [exhibits a substantial immunological reactivity]
binds specifically in a western blot analysis with a polyclonal rabbit antibody raised against a second polypeptide having an apparent molecular weight of 13 kDa as determined by SDS PAGE followed by visualization, [and]

wherein [being] said second polypeptide is [derived] from *Borrelia burgdorferi* B313, said second polypeptide [comprising] consists essentially of the amino acid sequence 1-167 of SEQ ID NO: 19,

and wherein said polyclonal rabbit antibody [exhibiting substantially no immunological reactivity] does not bind specifically in a western blot analysis with whole cell preparations from at least 95% of randomly selected *B. hermsii, B. crocidurae, B. anserina*, or *B. hispanica*,

with the proviso that said first polypeptide is [essentially] free from other *Borrelia*-derived antigens when it is identical in amino acid sequence to a third polypeptide which is a 13 kDa surface exposed polypeptide extracted from *Borrelia burgdorferi sensu lato*; and,
the first polypeptide optionally [being] is lipidated.

74. (Amended) The isolated first polypeptide according to claim 73, which [has] consists essentially of an amino acid sequence contained in a fourth polypeptide; wherein said fourth polypeptide is present in whole cell preparations of *Borrelia burgdorferi* B31, *Borrelia burgdorferi* B313, *Borrelia garinii* IP90, or *Borrelia afzelii* ACAl but is [substantially] absent from whole cell preparations of at least 95% of randomly selected *Borrelia hermsii*, *Borrelia crocidurae*, *Borrelia anserina*, or *Borrelia hispanica*.

75. (Amended) The isolated first polypeptide according claim 73, which [comprises] consists essentially of at least a portion of the amino acid sequence of a protein having an apparent molecular weight of 13 kDa; wherein said protein is present in whole cell preparations of *Borrelia burgdorferi* B31, *Borrelia burgdorferi* B313, *Borrelia garinii* IP90, or *Borrelia afzelli* ACAl but is [substantially] absent from whole cell preparations of at least 95%

of randomly selected *Borrelia hermsii*, *Borrelia crocidurae*, *Borrelia anserina*, and *Borrelia hispanica*.

76. (Amended) The isolated first polypeptide according to claim 73, which [comprises] consists essentially of at least one epitope; wherein said epitope is present in whole cell preparations of *Borrelia burgdorferi* B31, *Borrelia burgdorferi* B313, *Borrelia garinii* IP90, or *Borrelia afzelii* ACAI but is [substantially] absent from whole cell preparations of at least 95% of randomly selected *Borrelia hermsii*, *Borrelia crocidurae*, *Borrelia anserina*, and *Borrelia hispanica*.

77. (Amended) The isolated first polypeptide according to claim 73, which [comprises] consists essentially of at least one epitope of a protein having an apparent molecular weight of 13 kDa; wherein said protein is present in whole cell preparations of *Borrelia burgdorferi* B31, *Borrelia burgdorferi* B313, *Borrelia garinii* IP90, or *Borrelia afzelii* ACAI but is [substantially] absent from whole cell preparations of at least 95 % of randomly selected *Borrelia hermsii*, *Borrelia crocidurae*, *Borrelia anserina*, and *Borrelia hispanica*.

78. (Amended) The isolated first polypeptide according to claim 73, which [comprises] consists essentially of at least one amino acid sequence selected from the group consisting of: amino acid residues 19-27 in SEQ ID NO: 19, amino acid residues 33-36 in SEQ ID NO: 19, amino acid residues 41-47 in SEQ ID NO: 19, amino acid residues 95-104 in SEQ ID NO: 19, amino acid residues 138-147 in SEQ ID NO: 19, amino acid residues 174-179 in SEQ ID NO: 19, amino acid residues 19-26 in SEQ ID NO: 21, amino acid residues 32-35 in SEQ ID NO: 21, amino acid residues 40-47 in SEQ ID NO: 21, amino acid residues 94-101 in SEQ ID NO: 21, amino acid residues 137-146 in SEQ ID NO: 21, amino acid residues 174-178 in SEQ ID NO: 21, amino acid residues 18-26 SEQ ID NO: 23, amino acid residues 30-33 SEQ ID NO: 23, amino acid residues 39-46 SEQ ID NO: 23, amino acid residues 91-104 SEQ ID NO: 23, amino acid residues 137-145 SEQ ID NO: 23, and amino acid residues 173-177 in SEQ ID NO: 23.

79. (Not Amended) The isolated first polypeptide according to claim 73, which has an amino acid sequence identical to that of a protein having an apparent molecular weight of 13 kDa and being present in whole cell preparations of *Borrelia burgdorferi* B31, *Borrelia burgdorferi* B313, *Borrelia garinii* IP90, or *Borrelia afzelii* ACAI.

80. (Not Amended) The isolated first polypeptide according to claim 79, wherein the protein is present in fraction B from *Borrelia burgdorferi* B31, *Borrelia burgdorferi* B313, *Borrelia garinii* IP90, or *Borrelia afzelii* ACAI.

81. (Not Amended) The isolated first polypeptide according to claim 79, wherein the protein is the third polypeptide.

82. (Amended) The isolated first polypeptide [fragment] according to claim 73, which has an amino acid sequence exhibiting a sequence identity of at least 50% with an amino acid sequence selected from SEQ ID NO: 19, SEQ ID NO: 21, SEQ ID NO: 23, a subsequence of SEQ ID NO: 19 [containing] consisting essentially of at least 10 contiguous amino acids of SEQ ID NO: 19, a subsequence of SEQ ID NO: 21 [containing] consisting essentially of at least 10 contiguous amino acids of SEQ ID NO: 21, and a subsequence of SEQ ID NO: 23 [containing] consisting essentially of at least 10 contiguous amino acids of SEQ ID NO: 23.

83. (Amended) The isolated first polypeptide [fragment] according to claim 73, which is encoded by a nucleotide sequence exhibiting a sequence identity of at least 70% with a sequence selected from the group consisting of SEQ ID NO: 18, SEQ ID NO: 20, SEQ ID NO:22, a subsequence of SEQ ID NO: 18 [containing] consisting essentially of at least 12 contiguous nucleotides of SEQ ID NO: 18, a subsequence of SEQ ID NO: 20 [containing] consisting essentially of at least 12 contiguous nucleotides of SEQ ID NO: 20, and a subsequence of SEQ ID NO: 22 [containing] consisting essentially of at least 12 contiguous nucleotides of SEQ ID NO: 22.

84. (Amended) The isolated first polypeptide according to claim [93] 83, which [comprises] consists essentially of an amino acid sequence selected from the group consisting of SEQ ID NOs: 19, 21, and 23.

85. (Not Amended) The isolated first polypeptide according to claim 84, which is encoded by a nucleotide sequence selected from the group consisting of SEQ ID NOs: 18, 20, and 22.

86. (Not Amended) A fusion polypeptide comprising a first fusion partner and a second fusion partner; wherein the first fusion partner is the isolated first polypeptide according to claim 73.

87. (Not Amended) The fusion polypeptide according to claim 86, wherein the second fusion partner enhances the immunogenicity of the fusion polypeptide relative to the immunogenicity of a polypeptide not comprising said second fusion partner; or the second fusion

partner facilitates the expression of the fusion polypeptide in a host cell and/or subsequent purification of the fusion polypeptide.

88. (Not Amended) The fusion polypeptide according to claim 86, wherein the second fusion partner is at least one polypeptide selected from the group consisting of:

- a polypeptide selected from the group consisting of: amino acid residues 19-27 in SEQ ID NO: 19, amino acid residues 33-36 in SEQ ID NO: 19, amino acid residues 41-47 in SEQ ID NO: 19, amino acid residues 95-104 in SEQ ID NO: 19, amino acid residues 138-147 in SEQ ID NO: 19, amino acid residues 174-179 in SEQ ID NO: 19, amino acid residues 19-26 in SEQ ID NO: 21, amino acid residues 32-35 in SEQ ID NO: 21, amino acid residues 40-47 in SEQ ID NO: 21, amino acid residues 94-101 in SEQ ID NO: 21, amino acid residues 137-146 in SEQ ID NO: 21, amino acid residues 174-178 in SEQ ID NO: 21, amino acid residues 18-26 SEQ ID NO: 23, amino acid residues 30-33 SEQ ID NO: 23, amino acid residues 39-46 SEQ ID NO: 23, amino acid residues 91-104 SEQ ID NO: 23, amino acid residues 137-145 SEQ ID NO: 23, and amino acid residues 173177 in SEQ ID NO: 23;
- a lipoprotein selected from the group consisting of an outer membrane lipoprotein from *E. coli* and an outer membrane lipoprotein from OspA from *Borrelia burgdorferi sensu lato*;
- a viral protein selected from the group consisting of Hepatitis B surface antigen, Hepatitis B core antigen, and the influenza virus non-structural protein NS1;
- an immunoglobulin binding protein selected from the group consisting of protein A, protein G, and the synthetic ZZ-peptide;
- a T-cell epitope;
- a B-cell epitope;
- a bacterial fimbrial protein selected from the group consisting of pilus components pilin and papA, and
- a polypeptide selected from the group consisting of the maltose binding protein, glutathione S-transferase, ß-galactosidase, and polyhistidine.

89. (Not Amended) An immunological composition comprising the isolated first polypeptide according to claim 73, in an amount effective to elicit an immunogenic response in an animal or human to which the composition is administered, and a pharmaceutically acceptable carrier, diluent or vehicle; and optionally further comprising an adjuvant.

90. (Not Amended) The immunological composition according to claim 89, wherein the pharmaceutically acceptable carrier, diluent or vehicle is selected from the group consisting of sterile water, physiological saline, glucose, a polyalkalene glycol, and a triglyceride.

91. (Not Amended) The immunological composition according to claim 89 wherein the adjuvant is present and is selected from the group consisting of: aluminium hydroxide or phosphate (alum), a synthetic polymer of sugar, bacterial cells or components thereof, and a physiologically acceptable oil vehicle; wherein the bacterial cells or components thereof are *C. parvum* cells, or endotoxins or lipopolysaccharide components of gram-negative bacteria; and, the physiologically acceptable oil vehicle contains mannide mono-oleate or a perfluorocarbon.

92. (Not Amended) The immunological composition according to claim 90 wherein the adjuvant is present and is selected from the group consisting of: aluminium hydroxide or phosphate (alum), a synthetic polymer of sugar, bacterial cells or components thereof, and a physiologically acceptable oil vehicle; wherein the bacterial cells or components thereof are *C. parvum* cells, or endotoxins or lipopolysaccharide components of gram-negative bacteria; and, the physiologically acceptable oil vehicle contains mannide mono-oleate or a perfluorocarbon.

93. (Not Amended) The immunological composition according to claim 89, wherein the amount of the isolated first polypeptide is in the range of 1-1000 μg per dose unit.

94. (Not Amended) The immunological composition according to claim 89, wherein the amount of the isolated first polypeptide is in the range of between 2 and 750 μg per unit dose.

95. (Not Amended) The immunological composition according to claim 89, wherein the amount of the isolated first polypeptide is in the range of between 5 and 500 μg per unit dose.

96. (Not Amended) The immunological composition according to claim 89, wherein the amount of the isolated first polypeptide is in the range of between 7.5 and 250 μg per unit dose.

97. (Not Amended) The immunological composition according to claim 89, wherein the amount of the isolated first polypeptide is in the range of between 10 and 150 μg per unit dose.

98. (Not Amended) The immunological composition according to claim 89, wherein the amount of the isolated first polypeptide is in the range of between 10 and 100 μg per unit dose.

99. (Not Amended) The immunological composition according to claim 89, wherein the amount of the isolated first polypeptide is in the range of between 10 and 75 μg per unit dose.

100. (Not Amended) The immunological composition according to claim 89, wherein the amount of the isolated first polypeptide is in the range of between 10 and 50 μg per unit dose.

101. (Not Amended) The immunological composition according to claim 89 further comprising at least one additional *Borrelia* antigen.

102. (Not Amended) The immunological composition of claim 101, wherein the at least one additional Borrelia antigen is selected from the group consisting of OspA, OspB, OspC, OspD, OspE, OspF, OspG, PC, Oms28, Oms45, Oms 66, decorin binding protein (dbp), LpLA7, EppA, T5, S1, 26 kDa antigen, 39 kDa antigen, 66 kDa antigen, 79 kDa antigen, 85 kDa antigen, and 110 kDa antigen.

103. (Not Amended) An immunological composition comprising two non-identical isolated first polypeptides according to claim 73, in an amount effective to elicit an immunogenic response in an animal or human to which the composition is administered, and a pharmaceutically acceptable carrier, diluent or vehicle; and optionally further comprising an adjuvant.

104 (Not Amended) A diagnostic composition for the detection of *Borrelia burgdorferi sensu lato* in a sample; said composition comprising the isolated first polypeptide according to claims 73 in an amount effective to detectably react with any antibodies present in the sample directed against *Borrelia burgdorferi sensu lato*; and, the composition optionally further comprises a detectable label.

105. (Not Amended) A method for inducing an immunological response in an animal or a human, against *Borrelia burgdorferi sensu lato*; the method comprising administering to the animal an immunogenically effective amount of the immunological composition according to claim 89.

106. (Not Amended) A diagnostic kit comprising an isolated first polypeptide according to claim 73, and a means for detecting the isolated first polypeptide with antibody bound thereto.

108. (Not Amended) The immunological composition of claim 89 wherein the isolated first polypeptide is prepared by synthesizing the isolated first polypeptide by solid phase peptide synthesis or liquid phase peptide synthesis; or expressing, in a cell which does not natively express it, a nucleic acid fragment comprising a nucleotide sequence encoding the isolated first polypeptide.

109. (Not Amended) The immunological composition of claim 101 wherein the isolated first polypeptide is prepared by synthesizing the isolated first polypeptide by solid phase peptide synthesis or liquid phase peptide synthesis; or expressing, in a cell which does not natively express it, a nucleic acid fragment comprising a nucleotide sequence encoding the isolated first polypeptide.

110. (Not Amended) The immunological composition of claim 103 wherein the isolated first polypeptides are prepared by synthesizing the isolated first polypeptide by solid phase peptide synthesis or liquid phase peptide synthesis; or expressing, in a cell which does not natively express it, a nucleic acid fragment comprising a nucleotide sequence encoding the isolated first polypeptide.

111. (Not Amended) The diagnostic composition of claim 104 wherein the isolated first polypeptide is prepared by synthesizing the isolated first polypeptide by solid phase peptide synthesis or liquid phase peptide synthesis; or expressing, in a cell which does not natively express it, a nucleic acid fragment comprising a nucleotide sequence encoding the isolated first polypeptide.

Kindly cancel claim 107, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any etoppel as to equivalents.